

**EDITORIAL**

# Can Patient-specific Finite Element Models Enter Clinical Practice as a Decision Support System?

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The finite element method (FEM) is an engineering tool to assess the mechanical behavior of a structure under applied loads. In this method, the model is discretized, by mesh generation, into smaller parts called elements to assess the system response to the applied loads. This method was first applied for stress analysis of mechanical structures in the late 1950s (1). About fifteen years after its use in mechanical engineering, this new method got the application in biomedical engineering by analyzing the mechanical behavior of human femur bones (2). Although the FE method was preliminary used for stress analysis, it represents a versatile approach for quantitative analysis of different mechanical characteristics of bones or bone-implant systems (1). With the advent of faster computers, more advanced imaging modalities, and better FE software resulting in increased sophistication in 3D modeling, FE models have been greatly improved and the possibility and the possibility of creating a FE model that can closely mimic the geometry and material properties of bones of an individual patient, so-called a patient-specific model, is accessible (3). The objective of this editorial is to try to elucidate the advancements in and applications of patient-specific finite element modeling and discuss whether such models can give promising results in predicting the outcome of orthopedic surgeries and enter clinical practice.

With the advent of quantitative-CT (QCT), the relation of physical measures of bone density and its mechanical properties to Hounsfield units (HUs) was obtained, and driving non-homogeneous distribution of mechanical properties of bone became possible (4). Therefore, about two decades after the introduction of FEM in the orthopedic literature, the first patient-specific FE

model of the proximal femur with non-homogenous bone material properties was introduced by Keyak *et al.* in the late 1990s, bringing an evolution in the accuracy of FE models (5). In the patient-specific FEM, specific geometry, as well as material properties of the bone of an individual patient, can be modeled and individual's daily activities as the loading conditions can be applied to the model. Hence such models can be used as a clinical tool for orthopedic surgery planning rather than as a just research method (3).

The use of patient-specific FEM in clinical practice may be limited since advanced models using tetrahedral meshes requires a lot of manual work along with specific modeling software and engineering knowledge (6). Therefore, models with voxel-based meshes that can be highly automated while being robust are preferable. In this meshing method, a CT voxel is directly mapped to an equally sized single element with specified homogenized material properties depending on local bone density (3, 7). Different steps are involved in creating a patient-specific voxel-based FE model: first and the most labor-intensive step is the segmentation of the areas of interest (bones) in CT images based on the grayscale (GS) value of the corresponding voxels. Although there are several segmentation tools and algorithms available to automate this task, however, the algorithms solely cannot create an accurate geometry of the bone model and this step usually require a lot of manual intervention (3). Second, a voxel-based mesh is generated in which the size of each element is equal to the size of a predefined number of the voxels of the CT images. Third, material properties based on average HU or GS of each voxel using HU/GS-density and density-material properties relationships should be assigned to

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each element of the model. Fourth, specific boundary and loading conditions of each patient are applied and the biomechanical response of the model is analyzed. One great advantage of this method is differentiating cortical and cancellous bone as well as the non-homogeneous distribution of material properties based on local bone densities, within these two different types of bones. Since all the mechanical behavior of bone such as stress or strain distribution, failure load, and failure pattern depend on the material properties of the specimen, driving accurate distribution of material properties within the bone is one of the most crucial steps in the FE analysis. This non-homogeneous spatial distribution of material properties is particularly necessary for predicting the fracture location or failure pattern in metastatic and osteoporotic bones.

Patient-specific FE models have gained wide application in orthopedic biomechanics and are used successfully for the investigation of the mechanical behavior of proximal femur, vertebrae, and distal femur under simulated physiologic applied loads (6-13). Here, we review some recent studies in the field of patient-specific FE modeling and their clinical outcomes. Since 2005, this method is widely used for predicting the risk of pathological fracture in proximal femora (6, 7, 9). Keyak *et al.* first introduced and applied the nonlinear subject-specific FE method to predict the strength of proximal femora with or without metastatic lesions with sufficient precision and accuracy (9). Later on, in 2012, the ability of this method in predicting fracture location and failure load of proximal femora with or without metastatic lesions was compared with experimental data and predictions of clinical experts (14). Derikx *et al.*'s results showed FE models could accurately predict the failure load as measured in the experiment (14). It was observed that the failure location was in good agreement with experimental fracture lines for femora with metastatic lesions, but, FE models of intact femora predicted the fracture location, in most cases, different from the location observed in the experiment of the prediction of the fracture risk (14). While the assessment of initial bone strength is essential for the accurate prediction of the fracture risk, it appeared that this issue was ignored by clinicians who relied heavily on the cortical destruction, the size and location of the lesion for their fracture risk prediction (14). Sternheim *et al.* in 2018, assessed the utility of patient-specific linear FE analysis as a clinical tool to determine the need for prophylactic actions for patients with metastasis in their femur (15). They employed an ad hoc FE analysis on a retrospective cohort of fifty patients who were referred for prophylactic stabilization surgery based on Mirels' scoring system or clinical experiences. Their results showed 39% of patients were at low risk of fracture and may not have needed surgery (15). Bensa *et al.* in 2019 applied nonlinear subject-specific FE analysis to investigate the effect of metastatic lesions on the biomechanical behavior of the proximal femur. They showed FE models with voxel-based meshes can predict the stiffness and failure location in good agreement

with the corresponding experimental data (7). Ghouchani *et al.* in 2019, employed nonlinear subject-specific FE models to predict the failure locations and bone strength of distal femora following curettage and cementation and verified their models with the data of in-vitro experiments (13). Then, in 2020, they extended their validated models to investigate the effect of the size and location of tumoral defects in the distal femur on the post-operative fracture risk (16). The results of Ghouchani *et al.*'s study demonstrated there is a critical defect size that has a high risk of fracture following tumor curettage which was in agreement with the results of a retrospective study on 146 patients (16, 17). Sas *et al.* in 2020 employed the nonlinear subject-specific FE method to assess the strength of metastatic and healthy proximal femur using voxel-based meshes (6). Their results showed voxel-based meshes are robust, as precise and accurate as the state of the art tetrahedral FE models, and time-efficient due to having a high level of automation which is a very important factor for clinical usage (6).

The outcomes of the reviewed studies demonstrate that the FEM is a tool that, if used correctly, can lead to information that is eventually applied to the benefit of both patients and orthopedic surgeons as well as companies that produce bone implants (1). Information and concepts such as stress/strain distributions, bone-implant interface mechanics, and evaluation of the effect of one geometrical or mechanical parameter on the mechanical behavior of bone while maintaining other influential factors constant, which in many cases cannot be obtained in any other way. Although patient-specific models used in biomechanical studies have obtained good results and validation, this should be also considered that in most cases simplified loading on bones was applied and validation was based on in vitro experiments, while, in in-vivo conditions, complex loading and boundary conditions are applied on bones (9, 13, 16, 18). Also, bones have different material characteristics such as viscoelasticity, anisotropy, and nonlinearity besides non-homogeneity that all cannot be applied in the current FE methods. Therefore, this should be clear for the clinician what assumptions are made in the FE method and how they affect the accuracy of the FE outcome (3).

There are some complications with the patient-specific FEM that may limit its use, and have to be addressed before bringing this method into clinical practice. While the resolution of CT images and the consequent 3D model are dependent on the amount of X-ray radiation received, it should be kept in mind the potential harm of the high dose of X-ray. Since patient-specific FE modeling is aimed to be ultimately used in a clinical routine, CT image acquisition is limited to clinically allowable standards and ways to minimize the X-ray dose have to be explored (3). In addition, using patient-specific FE models as a clinical tool to decide whether a patient should be treated or how the treatment should be, requires adequate accuracy as well as ease of use (3). Moreover, the method should be automatic with minimum manual interventions to be applicable for many patients within

a limited time that is usually available for surgical interventions. Therefore, one important issue regarding the clinical use of patient-specific models is the time needed to analyze the models. Sas *et al.* reported less than 30 minutes for the average time to create, except for manual segmentation, and analyze a nonlinear patient-specific model for predicting femoral strength(6). Mirzaei *et al.* reported the average computational time for a patient-specific FE model of the proximal femur to be 5 minutes, considering linear FE analysis, while the run-time for a similar but nonlinear model would be around 8 hours on a regular desktop personal computer (18). Similarly, Derikx *et al.* reported the total time to generate a case-specific nonlinear model and to run the simulation around 8 hours (14). Bensa *et al.* used a highly automated method to perform image processing, modeling, and data evaluation (7). They reported an average time of 30 minutes for creating the 3D models, including the manual inputs, and the analysis time of 27 min using a conventional four CPU desktop PC (7). However, it should be noted that the expenditure time is highly related to the expertise of the person who creates the models, the software and computer used, and the number of elements in the model.

Patient-specific FEM has paved a way for non-invasively and pre-operatively prediction of the results of orthopedic surgeries. In this method, accurate geometry and specific material properties of patients along with their specific loads applied during their daily activities can be modeled to predict the mechanical behavior of their bones and the surgery outcome. Here, we reviewed several biomechanical studies employing patient-specific FEM with successful results in agreement with experimental data, highlighting the capability of this method for clinical use. However, FE models are currently hampered of entering clinical practice because the method involves a lot of manual work and therefore is time-consuming, requires engineering knowledge, and specific modeling software (6). In order to make this method a decision support system and clinically applicable tool, the models and analysis should be robust and fast with high level of automation. Moreover, analysis of the models need to be run a desktop PC or small work station (6). Finally, the reliability of patient-specific FE models has to be evaluated in real and in situ scanning conditions for more realistic, and complex loading scenarios (7).

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